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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

FLUE-CURED TOBACCO COOPERATIVE STABILIZATION CORPORATION
1304 Annapolis Drive
Raleigh, North Carolina 27608

and

THE COUNCIL FOR BURLEY TOBACCO, INC.
3070 Harrodsburg Road
Lexington, Kentucky 40503

and

UNIVERSAL LEAF TOBACCO COMPANY, INC.
1501 North Hamilton Street
Richmond, Virginia 23230

and

PHILIP MORRIS INCORPORATED
120 Park Avenue
New York, New York 10017

and

R.J. REYNOLDS TOBACCO COMPANY
401 Main Street
Winston-Salem, North Carolina, 27102

and

GALLINS VENDING COMPANY
715 Stadium Drive
Winston-Salem, North Carolina 27101

Plaintiffs,

vs.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Civil Action No. _____

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2. EPA's risk assessment of ETS, entitled "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders" ("ETS Risk Assessment"), formally designates ETS as a Group A carcinogen, the highest carcinogenic designation under EPA's scheme for classifying suspect carcinogens. The classification of ETS as a Group A carcinogen was intended to and in fact did have a substantial impact throughout the country, including but not limited to compelling increased restrictions on smoking by private entities and all levels of government. EPA's actions with regard to ETS violated express statutory restrictions on its authority in the Radon Act and violated statutory commands to convene and consult with specific advisory committees.

3. EPA's classification of ETS as a Group A carcinogen is wrong as a matter of law and science and, as such, is arbitrary and capricious. As demonstrated in this Complaint EPA was able to reach its conclusion only by manipulating and "cherry-picking" data, ignoring critical statistical studies and chemical analyses, failing to account for confounding factors and sources of bias, violating basic statistical principles designed to minimize the possibility that an apparent association is due to chance, and generally altering EPA's models, assumptions, and methodologies when use of the Agency's usual models, assumptions, and methodologies would not have supported its conclusions. The classification of ETS and the underlying risk assessment violated

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place of business in Richmond, Virginia. Universal Leaf purchases leaf tobacco from growers, processes it and sells it to cigarette manufacturers.

8. Plaintiff Philip Morris Incorporated ("Philip Morris") is a Virginia corporation with its principal place of business in New York, New York.

9. Plaintiff R.J. Reynolds Tobacco Company ("Reynolds") is a New Jersey corporation with its principal place of business in Winston-Salem, North Carolina.

10. Plaintiffs Philip Morris and Reynolds at all times relevant to this action, were and continue to be engaged in the manufacture and distribution of cigarettes.

11. Plaintiff Gallins Vending Company ("Gallins") is a North Carolina corporation with its principal place of business in Winston-Salem, North Carolina. Gallins is engaged in the distribution of cigarettes through its placement and servicing of vending machines containing cigarettes in various retail and other establishments throughout the Winston-Salem, North Carolina area.

12. Plaintiffs have been and will continue to be directly affected and injured by defendants' unauthorized and unlawful decision to classify ETS as a human carcinogen.

13. Defendant EPA is an independent agency of the Executive Branch established by Congress to coordinate and implement

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18. EPA thus has no authority either (i) to regulate indoor air quality, or (ii) to take any action, other than research, in preparation for such regulation. For this reason, the final regulatory classification of ETS as a Group A carcinogen is beyond EPA's authority. Such classification serves only impermissible regulatory purposes and therefore is activity expressly prohibited by the Radon Act.

19. The Radon Act required EPA to establish two new committees "to assist [it] in carrying out the research program for radon gas and indoor air quality." The first committee, the "Federal Agency Advisory Committee," was to be composed of representatives from various federal agencies concerned with indoor air. The second committee, the "Radon Act Advisory Committee," was to be composed of representatives from the states, the scientific community, industry, and public interest organizations. In violation of the Radon Act, EPA has never established the Radon Act Advisory Committee.

20. Contrary to the requirements of the Radon Act, EPA initiated, prepared, and reviewed the ETS Risk Assessment without consulting with the Federal Agency Advisory Committee or, obviously, the Radon Act Advisory Committee.

21. As a result of EPA's violation of the requirements of the Radon Act, representatives from industry, the states, the scientific community, and public interest organizations were precluded from assisting EPA in the manner required by Congress.

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expressed as relative risks. A relative risk is the ratio of the disease incidence rate in the exposed group to the incidence rate in the unexposed group. A relative risk of 1.0 indicates that the observed disease incidence rate in the exposed group is the same as that in the unexposed group. A relative risk above 1.0 indicates that the disease incidence rate is greater in the exposed group, while a relative risk less than 1.0 indicates that the disease incidence rate is smaller in the exposed group.

25. In recognition of the complexity of epidemiology and to ensure consistency in its methodology, EPA has adopted certain criteria by which it evaluates epidemiologic data. These criteria are set forth in EPA's own cancer risk assessment guidelines, "Guidelines for Carcinogen Risk Assessment," 51 Fed. Reg. 33992 (Sept. 24, 1986) (the "Risk Assessment Guidelines"). The Risk Assessment Guidelines provide that before a conclusion regarding whether an exposure causes a disease (a causal inference) can be based upon epidemiologic data, three criteria must be met: (i) the apparent statistical association must be unlikely to be produced by chance; (ii) the possibility of confounding (i.e. the role of other actual or potential factors in the apparent association) must have been considered and ruled out as an explanation for the association; and (iii) there must be no identified bias that could explain the apparent association. 51 Fed. Reg. 33999. In addition, EPA admits in its ETS Risk Assessment that epidemiologic data must also be assessed

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interval calculated with a 95% confidence level, for example, is referred to as a 95% confidence interval. An apparent association or relative risk is said not to be statistically significant at the 95% confidence level unless the entire range of the 95% confidence interval for that risk is above or below 1.0. By generally accepted scientific convention, a 95% confidence level is required in epidemiologic studies to judge an association as statistically significant.

28. EPA analyzed 30 published epidemiologic studies when classifying ETS as a Group A carcinogen. The studies primarily address whether a woman's risk of lung cancer may be statistically correlated with whether her spouse smokes. The studies do not measure actual ETS exposure. Instead, they rely on questionnaire responses as to whether a woman's spouse smokes, thereby treating reports of spousal smoking as a surrogate for actual or measured ETS exposure.

29. Of the 30 published ETS studies EPA relied upon, 11 were conducted in the United States. As originally reported, none of the U.S. studies found an overall risk estimate for lung cancer that was statistically significant.

30. Of the remaining studies conducted in seven countries other than the United States, 13 found no overall statistically significant association between spousal smoking and lung cancer as originally reported. Put another way, of the 30 studies reviewed by EPA, 24 -- a full 80% -- as originally reported do

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also gathered data on male lung cancer risk and spousal smoking and, of these, only one, a Japanese study by Hirayama that is methodologically flawed on other grounds, is statistically significant even at the lower confidence level. Twelve of fourteen reported studies that have examined workplace ETS exposure and lung cancer risk have reported no statistically significant association at the lower confidence level. Similarly, 12 of 13 studies that have examined childhood ETS exposure and adult lung cancer risk fail to show a statistically significant association at that level.

34. The large number of studies, both those considered by EPA and those EPA refused to consider, which report no overall statistically significant association between ETS and lung cancer, overwhelm the few studies that EPA claims demonstrate an association and suggest that those few results may simply be the result of chance. When this evidence is coupled with EPA's choice of a confidence level which doubles the risk of an association due to chance being labeled statistically significant, chance becomes the likely explanation for any statistical association claimed by EPA between ETS and lung cancer.

(ii) Confounding

35. Confounding of data exists when an association between a disease and an exposure to one agent can be explained, in whole or in part, by an exposure to a second agent that is associated

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data. Instead, EPA deemed the criterion satisfied largely because it claimed to be unable to identify any single confounding factor that in itself would explain the apparent association between ETS and lung cancer which appeared in EPA's analysis. EPA's methodology falls well short of the Guidelines' requirement to "rul[e] out" the possibility of confounding.

(iii) Bias

39. Bias in statistics refers to any trend in the design, collection, analysis, interpretation or publication of statistical data that causes or may tend to cause a systematic distortion of the true nature of the relationship studied.

40. Both the Risk Assessment Guidelines and accepted epidemiologic principles require that bias must be excluded as an explanation for an observed association before it can be concluded that a statistically significant association exists. Various sources of bias, including publication bias and respondent bias, could explain any association claimed by EPA between ETS and lung cancer.

41. EPA recognized only one source of bias in its Risk Assessment -- the tendency of smokers to misrepresent themselves as nonsmokers ("smoking status misclassification bias") -- and chose to adjust for it by using an unpublished scientific model that contains numerous mathematical and conceptual inconsistencies, including assumptions based on nonrepresentative data. If EPA had used representative data, EPA's own analysis

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Risk Assessment, acknowledged the weakness of the association found by EPA when he noted to reporters at a press conference called to publicize the draft that the risk of ETS was "probably much less than you took to get here through Washington traffic."

45. In other contexts, EPA has concluded that relative risks greater than the risks claimed by EPA for ETS were insufficient to classify a potential carcinogen as a Group A carcinogen. For example, in a draft report on electromagnetic fields, the EPA concluded that, "[t]he association between cancer occurrence and exposure to either ELF or RF fields is not strong enough to constitute a proven causal relationship, largely because the relative risks in the published reports have seldom exceeded 3.0 in both childhood residential exposures and in occupational situations." U.S. EPA, Office of Health and Environmental Assessment, Evaluation of the Potential Carcinogenicity of Electromagnetic Fields, EPA/600/6-90/005A, Workshop Review Draft, June, 1990. The 1.19 relative risk reported for ETS by EPA is less than one-tenth of the 3.0 relative risk found "not strong enough" by the SAB with regard to electromagnetic fields.

46. Because any statistical associations between ETS and lung cancer relied upon by EPA are so weak, it is very likely that they are produced by chance, bias, or confounding.

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causal inferences. Inconsistency among studies suggests that chance, bias, or confounding has produced the associations reported, not exposure to the substance under assessment.

52. The epidemiologic studies of spousal smoking and ETS are remarkably inconsistent. The studies' results vary widely by geographic area and the magnitudes of the reported associations vary by almost 300%. Without considering the requirement of statistical significance, six studies report associations above 2.0 while six studies report associations below 1.0. One study (Wu-Williams) reports a statistically significant negative association between ETS and lung cancer.

(b) EPA's Meta-Analysis of Epidemiologic Studies Provides No Basis for a Group A Classification

53. Recognizing that analysis of the individual epidemiologic studies could not support a Group A classification, EPA combined or pooled select portions of the data from the epidemiological studies using a controversial technique known as meta-analysis to create evidence of an association between lung cancer and ETS. This exercise not only did nothing to eliminate bias, confounding, and methodologic flaws in any of the individual epidemiologic studies, but it introduced new and different errors and flaws into the analysis.

54. First, relying solely on data regarding U.S. women and employing its unorthodox confidence level, EPA calculated a pooled relative risk estimate of 1.19 which is extremely weak.

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b. EPA included certain reported data from an incomplete study (Fontham, 1991). Only the first three years of the five years scheduled have been completed and publication occurred before additional planned steps of verification had been undertaken. Although EPA included certain data from this incomplete study, it failed to include data relating to confounding factors which had been collected by the study's authors.

c. EPA violated its own criteria for determining what data to select with respect to one study (Janerich). Specifically, EPA used unadjusted risk estimates from household exposure from Janerich while it used adjusted risk estimates from spousal exposure from all other studies from which adjusted risk estimates could be derived.

57. Fourth, EPA failed to adjust adequately for smoking status misclassification bias, which is known to inflate the apparent association observed in studies of spousal smoking and lung cancer. Although EPA acknowledged this one source of bias and purported to adjust for it, EPA used a method of adjustment based on unrepresentative data instead of more representative data. EPA's use of these unrepresentative data resulted in an extremely low and unrealistic rate of adjustment that is not representative of the U.S. population for this crucial variable.

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(2) EPA Improperly Relied Upon a Proxy Substance to Justify Its Group A Classification

59. EPA also attempted to support its decision to classify ETS as a Group A carcinogen on an independent ground: analysis of a proxy substance. Specifically, EPA claimed that similarities between ETS and mainstream smoke (the smoke inhaled by a smoker), coupled with the assumption that any exposure to mainstream smoke poses a lung cancer risk, justified a Group A classification. EPA's classification on this basis is arbitrary and capricious.

60. First, EPA ignored the fact that ETS is not the equivalent of mainstream smoke. ETS is a highly dilute, complex and dynamic mixture of sidestream smoke ("SS"), exhaled mainstream smoke ("MS") and some diffused tobacco smoke emanating from the tobacco rod. Very few of the chemical constituents identified in mainstream smoke have been identified in ETS in ambient air. The general physical and chemical properties of the two smokes, including particle size, pH, constituent-phase distribution, and other physicochemical traits, differ significantly.

61. As recognized by the public health community, the multiple, pervasive and demonstrable differences between ETS and MS preclude any rational analysis of ETS using a proxy study of data on mainstream smoke. The Surgeon General concluded in 1986 that knowledge of MS chemical composition is of limited assistance in evaluating ETS: "Comparison of the relative

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a. Certain ETS constituents such as particulate matter and ambient nicotine can be measured in the ambient air. Based on those data, scientists have consistently estimated that an ETS exposed nonsmoker is exposed to the range of one to five cigarette equivalents per year.

b. According to a recent published review, data from several epidemiologic studies on active smoking suggest that smoking four to five cigarettes per day is not likely to be associated with a statistically significant increased risk of lung cancer.

c. Differences in retention can further expand these dosimetric differences. For example, it is estimated that the average ETS exposed person appears to retain between 10,000 and 100,000 times less smoke particulate matter than a cigarette smoker.

d. EPA's assumption, that no threshold exists for ETS exposure, relies solely on active smoking studies which have as their lowest exposure range 1-7, 1-9, 1-14 or <20 cigarettes smoked per day. All of these ranges are far in excess of the highest dose conceivably attributable to ETS.

65. Moreover, in the absence of a clear congressional mandate to the contrary, EPA is required to make a finding that a risk is significant before taking such action as classifying ETS as a Group A carcinogen. EPA's "no-threshold" assumption is an insufficient basis upon which to make such a finding. Indeed, if

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classifying potential carcinogens. Members of the general public, including plaintiffs, have a legitimate expectation that the guidelines will be followed and are justified in relying on them.

68. As set out above, EPA has violated the Risk Assessment Guidelines by failing to rule out the possibility that any association between spousal smoking and lung cancer is attributable to chance, confounders, or bias, and by failing to consider the absence of a strong association or a dose-response relationship. In addition, the EPA's classification of ETS as a Group A carcinogen violates the Risk Assessment Guidelines in at least six other respects.

69. First, the Risk Assessment Guidelines require EPA to ensure that "[s]tudies are evaluated according to sound biological and statistical considerations and procedures." 51 Fed. Reg. at 33994. EPA violated accepted statistical principles by performing a meta-analysis on noncomparable data and by using an unorthodox confidence level in place of the scientifically accepted 95% level. Moreover, EPA engaged in unjustified biological assumptions in applying studies on mainstream smoke to ETS.

70. Second, the Risk Assessment Guidelines require that the EPA's evidence from epidemiologic studies be "sufficient" before ETS can be classified as a Group A carcinogen. 51 Fed. Reg. at 34000. All of the epidemiologic studies conducted in the United

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on home exposure during childhood reported in 10 of the 30 studies, (iii) the data from numerous published studies which have measured ETS constituents in indoor air, (iv) the data on the physical and chemical distinctions between ETS and MS, and (v) data on identified sources of bias and confounding factors.

72. Fourth, the Risk Assessment Guidelines require the EPA to "fully present" all relevant scientific information in the ETS Risk Assessment. 51 Fed. Reg. at 33992. The ETS Risk Assessment fails to "fully present" critical scientific information. For example, the EPA has not informed the public of the fragility of the meta-analysis. That analysis depends entirely, among other things, on (1) the determination to evaluate chance at a lower confidence level; (2) the exclusion of the largest U.S. study ever; and (3) the employment of a series of unjustified assumptions and unproven and unaccepted methods.

73. Fifth, the Risk Assessment Guidelines require the EPA to "use the most scientifically appropriate interpretation to assess risk." 51 Fed. Reg. at 33992. EPA did not. Instead, EPA used an unconventional statistical significance level, combined noncomparable studies in a meta-analysis, relied upon inappropriate assumptions to manipulate the data, such as when adjusting for smoker misclassification, and inappropriately analogized ETS exposure to cigarette smoking. Had EPA employed "the most scientifically appropriate interpretation" of the available data, it could not have classified ETS as a Group A carcinoge

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(2) Exposure Assessment Guidelines

77. In 1992, the EPA issued its Exposure Assessment Guidelines, which govern EPA exposure assessments and their use in risk assessments. Like the Risk Assessment Guidelines, the purposes of the Exposure Assessment Guidelines are "to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management." 57 Fed. Reg. at 22888.

78. The ETS Risk Assessment violated the Exposure Assessment Guidelines in at least three respects.

a. First, the Exposure Assessment Guidelines require that "exposure estimates along with supporting information . . . be fully presented in Agency risk assessment documents." 57 Fed. Reg. at 22888. Numerous studies providing ETS exposure estimates are omitted from the Risk Assessment.

b. Second, the Exposure Assessment Guidelines direct EPA to "identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment." 57 Fed. Reg. at 22888. EPA made no effort to identify the numerous uncertainties, assumptions and limitations of its exposure assessment, including the

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D. Classification of ETS as a Group A Carcinogen Constitutes Final Agency Action

80. In classifying and publicizing ETS as a Group A carcinogen, EPA expected and intended its action to have a substantial regulatory impact resulting in the restriction of smoking in the workplace and in public. Then-EPA Administrator Reilly stated that classifying ETS as a human carcinogen was "one of the biggest decisions I ever will make." He expressed the hope that the classification "will have profound reverberations in the country" and that no further action by any other government agency will be necessary for the EPA report to have an impact because "the liability question will drive it." Mr. Reilly concluded that "the government has spoken on the question."

81. EPA's decision to classify ETS as a Group A carcinogen has resulted in and continues to result in exactly the regulatory impact intended by EPA. By classifying ETS as a human carcinogen, EPA exerted tremendous pressure on both private and public entities to restrict smoking in the workplace and in public -- pressure that the entities believed could not be ignored. Specifically, as a direct result of the EPA's classification of ETS as a Group A carcinogen, private entities, fearing liability, have felt compelled to institute restrictions or total bans on smoking in their buildings. The ETS Risk Assessment also has prompted public agencies to institute or consider instituting similar smoking restrictions or bans.

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a. EPA intended that its January 7, 1993, classification of ETS as a Group A carcinogen be a final and unequivocal agency conclusion and decision. As Administrator Reilly stated, "[t]he government has spoken on the question."

b. The ETS Risk Assessment embodying the classification was formally released by the EPA administrator.

c. EPA is contemplating no further action regarding the classification of ETS as a Group A carcinogen.

E. Plaintiffs Have Been Injured By EPA's Actions

86. The classification of ETS as a Group A carcinogen was intended to and in fact did falsely disparage plaintiffs' products and their reputations and resulted in a loss of good will. The classification also was intended to and in fact did result in the imposition of greater smoking restrictions in the workplace and public areas. These smoking restrictions, based on a classification of ETS as a Group A carcinogen without scientific foundation, have resulted and will continue to result in decreased sales and use of cigarettes and, concomitantly, decreased use and sales of tobacco. For example, plaintiff Gallins has removed cigarette vending machines from premises where they had been placed at the request of the owners of the premises. On information and belief, it has also been precluded

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now that the [EPA] has declared that secondhand smoke causes cancer."

c. Restaurants have also initiated smoking bans. For example, in specific reliance on EPA's classification, the California Restaurant Association, on January 7, 1993, endorsed legislation which would ban smoking in the workplace and all public places.

d. The Board of Directors of the Building Owners and Managers Association International, representing more than 5 billion square feet of North American office space, passed a resolution supporting a federal ban on smoking in the workplace.

e. The Governors of Kentucky and California have already issued executive orders that make those states' public smoking laws more restrictive. Other states, including Colorado, Delaware, Hawaii, Illinois, Iowa, Kansas, Maryland, Missouri, Minnesota, Montana, Nebraska, New York, Ohio, Texas, Utah, Vermont, and Virginia have proposed legislation to ban or restrict smoking in workplaces and other public areas.

f. Legislation was introduced in Congress that would prohibit smoking in all structures owned or leased for use by a federal agency, including the Executive and Judicial Branches, "Preventing Our Federal Building Workers and visitors Exposure to Deadly Smoke (PRO-FEDS) Act of 1993."

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93. Classification of ETS as a Group A carcinogen does not constitute research as authorized by the statute. EPA's classification of ETS as a Group A carcinogen serves no legitimate research purpose, but is designed and intended solely to achieve a substantial regulatory impact and effect. EPA's classification of ETS has in fact had a substantial regulatory impact and effect.

94. EPA exceeded its statutory authority under Sections 403 and 404 of the Radon Act by classifying ETS as a Group A carcinogen.

95. EPA further exceeded its authority under the Radon Act by deciding to classify ETS as a Group A carcinogen without making a finding as to whether exposure to ETS poses a significant risk.

96. EPA also violated the Radon Act by not properly establishing the Radon Act Advisory Committee mandated by Section 403(c) of the Radon Act. Under the Radon Act, that Committee is to provide EPA with the input from industry and the public to assist the defendants in carrying out research programs. Because no such committee was ever formed, EPA's classification of ETS and the ETS Risk Assessment also violate the Radon Act and exceed EPA's statutory authority.

97. Under Section 403(c) of the Radon Act, the Administrator was also required to establish a Federal Agency Advisory Committee composed of individuals representing Federal

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Advisory Committee are unlawful because they are in excess of the authority of the defendants;

(C) To declare that the classification of ETS as a Group A carcinogen and the issuance of the ETS Risk Assessment were unlawful and in violation of statutory procedures;

(D) To grant an injunction requiring EPA to withdraw its classification of ETS as a Group A carcinogen and to withdraw its ETS Risk Assessment; and

(E) To grant plaintiffs such additional relief that the Court may deem just and proper.

COUNT II

THE CLASSIFICATION OF ETS AS A GROUP A CARCINOGEN IS ARBITRARY, CAPRICIOUS, AND OTHERWISE NOT IN ACCORDANCE WITH LAW

100. Plaintiffs incorporate herein by reference paragraphs 1 through 88 of the complaint.

101. EPA's decision to classify ETS as a Group A carcinogen and the underlying ETS Risk Assessment was based on incomplete, irrelevant, and inconsistent data.

102. In classifying ETS and promulgating the ETS Risk Assessment, EPA ignored available, persuasive scientific data contrary to its conclusions.

103. The classification of ETS as a Group A carcinogen and the ETS Risk Assessment are based on models, assumptions, and methodologies that are inaccurate, flawed, and not accepted by the scientific community.

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COUNT III

EPA VIOLATED THE APA BY FAILING TO COMPLY WITH ITS OWN GUIDELINES

107. Plaintiffs incorporate herein by reference the allegations contained in paragraphs 1 through 88 of this complaint.

108. In classifying ETS as a human carcinogen, EPA violated the Risk Assessment Guidelines.

109. In classifying ETS as a human carcinogen, EPA violated the Exposure Assessment Guidelines.

110. EPA violated its own guidelines as alleged above, individually and collectively, for the purpose of reaching a desired conclusion (that ETS is a Group A carcinogen) that could not have been reached but for such violations.

111. As a result of EPA's violations of its own guidelines, the classification of ETS as a Group A carcinogen was "without observation of procedure required by law" and therefore violated Section 706(2)(D) of the APA.

112. As a direct and proximate cause of EPA's unlawful acts, plaintiffs have been seriously injured as alleged herein.

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116. In classifying ETS as a Group A carcinogen and issuing the ETS Risk Assessment, EPA also violated its Risk Assessment Guidelines, and its Exposure Assessment Guidelines.

117. Plaintiffs had a legitimate expectation that EPA would comply with the Radon Act and with EPA's own guidelines. Plaintiffs relied on the provisions of the Radon Act and EPA's guidelines for protection from arbitrary and capricious actions, including classification of ETS as a Group A carcinogen and the underlying risk assessment.

118. EPA was only able to reach its desired conclusion by violating the Radon Act and the agency's guidelines. EPA could not have concluded that ETS was a Group A carcinogen but for such violations.

119. As a direct and proximate cause of EPA's violations of the Radon Act and the agency's guidelines, plaintiffs have been seriously injured and deprived of property interests, including but not limited to loss of good will and sales.

WHEREFORE, plaintiffs pray this Court grant plaintiffs the following relief:

(A) To declare that EPA's classification of ETS as a Group A carcinogen and the ETS Risk Assessment violate the guarantee of due process of law in the United States Constitution, U.S. Const. amend. V.;

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